

describes the invention. Accordingly, reconsideration and withdrawal of the objection to the Abstract are requested.

II. In the Specification

The disclosure is objected to because it contains an informality on line 13 of page 1. Applicants disagree that the tense of the word "press" is incorrect. The word "press" in this context is used as an adjective describing the noun "fit". A tense is an attribute of a verb, thus it is not applicable to this instance of "press" which is an adjective. Therefore, the word "press" on page 1, line 13 cannot have an incorrect tense.

The Applicants have also amended the specification on page 7, line 16-page 8, line 5 to reflect the status of CFLEX and KRATON as trademarks.

The specification has been objected to for failing to provide antecedent basis for claimed subject matter including shapes of the finger tab portion. Applicants amend the application at page 8, lines 6-16 to provide proper antecedent basis for this claimed subject matter. Applicants believe that no new matter has been added because the subject matter was part of the original specification in claim 19. Accordingly, reconsideration and withdrawal of the objection to the specification are requested.

III. Claims Rejected Under 35 U.S.C. § 112, second paragraph

Claims 19, 24, and 30 stand rejected under 35 U.S.C. § 112, second paragraph for being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner states that claims 19, 24 and 30 fail to list the potential shapes in the alternative therefore leaving the claims indefinite. Applicants respectfully disagree.

Claims 19, 24 and 30 use the conjunction "and" to define a set of shapes for a tab. This set includes all of the items in the list, thus they are properly joined by the conjunction "and." The phrase "one of" used with the clearly defined sets "rectangular, cylindrical, spherical, and square" clearly sets forth the subject matter which the Applicants regard as the invention. The use of the disjunctive "or" in place of "and" would in fact not clearly delineate a set of shapes that the tabs could be "one of." Accordingly, reconsideration and withdrawal of the indefiniteness rejection of claims 19, 24 and 30 are requested.

Claims 25-30 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner states that "the first finger tab" and "the second finger tab" in claim 25 lack antecedent basis. Applicants have amended claim 25 to properly use an indefinite article. Accordingly, reconsideration and withdrawal of the indefiniteness rejection of claims 25-30 are requested.

IV. Claims Rejected Under 35 U.S.C. § 102

Claims 16 and 18-24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,188,605 issued to Sleep (hereinafter "Sleep"). Applicants respectfully disagree for the following reasons.

It is axiomatic that to anticipate a claim each element of the claim must be taught by a single reference. Claim 16 includes the elements of a hinge portion between the finger tabbed portion and the tube portion. The Examiner states that Sleep teaches a hinge portion 60. However, reference number 60 refers to a "'v' shaped notch 60 that narrows to the line of weakness 52." See Sleep Col. 4, lines 1 and 2. A notch is not the structural equivalent of a hinge. A notch is a space defined by a structure, whereas a hinge is a positive recitation of a structure

that facilitates the relative movement of other structures. Thus, the Examiner has failed to indicate and the Applicants have been unable to discern any part of Sleep that teaches a hinged portion. Accordingly, reconsideration and withdrawal of the anticipation rejection of claim 16 are requested.

In regard to claims 18-20, these claims depend from independent claim 16 and incorporate the limitations thereof. Thus, at least for the reasons mentioned in regard to claim 16, these claims are not anticipated by Sleep. Accordingly, reconsideration and withdrawal of the anticipation rejection of claim 16 are requested.

In regard to claim 21, this claim as amended includes the elements of a tabbed portion and tube portion that are formed as a single integral piece. Sleep does not teach these elements of claim 21. Rather, Sleep teaches that “enlarged tube 44 and manipulator 54 are injection molded in a single mold and physically connected to the tube 40 by ultrasonic welding.” See Sleep, Col. 3, lines 65-68. Therefore, manipulator portion 54 is not formed as a single integral piece with a tube portion 40. Further, Applicants note that enlarged tube portion 44 does not have a score line. Rather, enlarged tube 44, as well as tube 40, define a line of weakness 52 extending along the length of the insertion tool 10 that is, preferably, a slit running completely through a wall of the catheter insertion tool. See Col. 3, lines 59-62. Thus, Sleep teaches a slit running the length of the insertion tool 10 through a wall of tubes 44 and 40 and not a set of slits which define a score line. Therefore, Sleep does not teach each of the elements of claim 21. Accordingly, reconsideration and withdrawal of the anticipation rejection of claim 21 are requested.

In regard to claim 22-24, these claims depend from independent claim 21 and incorporate the limitations thereof. Thus, at least for the reasons mentioned in regard to claim 21, these

claims are not anticipated by Sleep. Accordingly, reconsideration and withdrawal of the anticipation rejection of claims 22-24 are requested.

Claims 25 and 28-30 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Number 5,167,634 issued to Corrigan, Jr. et al. (hereinafter "Corrigan").

In regard to claim 25, this claim includes the elements of the first and second finger tabs being formed in a single integral piece with the tube. Corrigan does not teach this element of claim 25. In fact, Corrigan teaches away from forming the finger tabs and tube in a single integral piece. Instead, Corrigan teaches "wings 14 also are bonded to sheath 12 at proximal end 20 of tube 18. A pair of wings 14 are bonded to respective peelable sheath portions 28." See Corrigan, col. 4, lines 59-61. Thus, Corrigan teaches a set of wings 14 that are formed separately from the sheath 12 and subsequently bonded to the sheath. Therefore, Corrigan does not teach or suggest each of the elements of claim 25. Accordingly, reconsideration and withdrawal of the anticipation rejection of claim 25 are requested.

In regard to claims 28-30, these claims depend from independent claim 25 and incorporate the limitations thereof. Thus, at least for the reasons mentioned in regard to claim 25, Corrigan does not teach each of the elements of these claims. Accordingly, reconsideration and withdrawal of the anticipation rejection of claims 28-30 are requested.

V. Claims Rejected Under 35 U.S.C. § 103

Claim 17 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Sleep, in view of U.S. Patent No. 5,263,938 issued Orr, et al. (hereinafter "Orr"). Applicants respectfully disagree for the following reasons.

In order to establish a *prima facie* case of obviousness, the Examiner must show that each element of the claim is taught or suggested by the combined references. In regard to claim 17, this

claim depends from independent claim 16 and incorporates the limitations thereof. Thus, at least for the reasons mentioned in regard to claim 16, Sleep does not teach each of the elements of claim 17, including a hinged portion between the finger tabbed portion and the tube portion. Orr does not cure this defect of Sleep. The Examiner has not indicated and the Applicants have been unable to discern any part Orr that teaches or suggests a hinged portion between a finger tabbed portion and a tube portion. Thus, Sleep, in view of Orr does not teach or suggest each of the elements of claim 17. Accordingly, reconsideration and withdrawal of the obviousness rejection of claim 17 are requested.

Claim 26 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Corrigan in view of U.S. Patent No. 5,782,817 issued to Franzel, et al. (hereinafter "Franzel").

Claims 26 depends from independent claim 25 and incorporates the limitations thereof. Thus, at least for the reasons mentioned in regard to claim 25, Corrigan does not teach or suggest each of the elements of claims 26, namely, a first finger tabbed and second finger tab formed as a single integral piece with a tube. Franzel does not cure this defect of Corrigan. The Examiner has failed to indicate and the Applicants have been unable to discern any part of Franzel that teaches or suggests forming a first and second finger tab as a single integral piece with a tube. Accordingly, reconsideration and withdrawal of the obviousness rejection of claim 26 are requested.

Claim 27 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Corrigan in view of Orr. Applicants respectfully disagree for the following reasons.

Claim 27 depends from independent claim 25 and incorporates the limitations therefore. Thus, at least for the reasons mentioned in regard to claim 25, Corrigan does not teach or suggest each of the elements of claim 27, namely that a first finger tab and second finger tab are formed as

a single integral piece with a tube. Orr does not cure this defect of Corrigan. The Examiner has not identified and the Applicants have been unable to discern any part of Orr that teaches or suggests a first and second finger tab formed as a single integral piece with the tube. Therefore, Corrigan, in view of Orr, does not teach or suggest each of the elements of claim 27. Accordingly, reconsideration and withdrawal of the obviousness rejection of claim 27 are requested.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending, namely claims 16-30 patentably define the subject invention over the prior art of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes that a telephone conference would be useful in moving the application forward to allowance, the Examiner is encouraged to contact the undersigned at (310) 207 3800.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

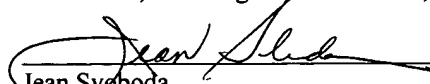
Dated: 1/28, 2003


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CERTIFICATE OF MAILING:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Box Non-Fee Amendment, Assistant Commissioner for Patents, Washington, D.C. 20231, on January 28, 2003.


Jean Svoboda

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE ABSTRACT

The abstract has been amended as follows:

A method and an apparatus for forming a one-piece introducer in which at least one finger tab is formed at one end of a tube. The apparatus is formed from a molten polymer fed into the cavity of a mold. The cavity of the mold has a portion that forms a tube and a portion that forms a tab.

IN THE SPECIFICATION

Please amend the specification starting at page 7 line 16 to state:

The materials that may be used for injection molding of the one-piece introducer include liquid crystal polymers such as that which is commercially available as VECTRA™ from TICONA™, a division of Hoechst (Summit, New Jersey) and XYDAR™ commercially available from Amoco Polymers, Inc. located at Alpharetta, Georgia. Additionally, other polymers may be used such as polyetheramides, polycarbonate, polyester with glass fiber, polyester with carbon filler, polyamide with glass fiber, thermoplastic elastomers, *e.g.*, CFLEX™, commercially available from Consolidated Polymer Technology located in Largo, Florida; KRATON™ commercially available from GLS Corporation, Thermoplastic Elastomers Division located in McHenry, Illinois; polyurethane, and SANTOPRENE™ commercially available from Advanced Elastomer Systems located in Akron, Ohio; polyolefins and polyamide with carbon filler. Liquid crystal polymer is the preferred material to be used in this process.

Please amend the specification starting at page 8 line 6 to state:

Figure 3 illustrates one embodiment of the invention for introducing molten polymer into mold 100. The molten polymer is introduced into mold 100 using a variety of known methods

such as injection molding, multi-injection molding, co-injection molding, gas assist molding or other suitable method. **Figure 3** illustrates mold 100 including first and second sections 115a and 115b and third section 190 that are mated together. The cavity formed by mold 100 includes tube portion 250 having a beveled distal tip 245, a finger tab portion 270, and a hinge 260 between tube portion 250 and finger tab portion 270, and a safety valve 247. Hinge 260 and tube portion 250 that are formed from this process are hollow. Hinge 260 may also be solid. In one embodiment, the tab portion 220 of the cavity may define a rectangular, cylindrical, spherical or square shaped tab.

IN THE CLAIMS

Please amend the claims as follows:

21. A one-piece introducer comprising:
- at least one finger tab portion;
 - a tube portion having a scoreline, wherein the at least one finger tab portion and the tube portion are [seamless]formed as a single integral piece.
25. A one-piece introducer comprising:
- a tube;
 - [the] a first finger tab and [the] a second finger tab formed at a proximal end of the tube
 - [without seams]as a single integral piece with the tube; and
 - a scoreline formed on the tube.